



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/467,928	12/21/1999	DAVID GAILLAC	017753-120	2965

21839 7590 10/06/2003

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

PARKIN, JEFFREY S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/06/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/467,928

Applicant(s)

GAILLAC ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Amendment

37 C.F.R. § 1.114

1. A request for continued examination under 37 C.F.R. § 1.114, including the fee set forth in 37 C.F.R. § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. § 1.114, and the fee set forth in 37 C.F.R. § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. § 1.114. Applicants' submission filed on 28 April, 2003, has been entered.

Status of the Claims

2. Acknowledgement is hereby made of receipt and entry of the amendment submitted 28 April, 2003, wherein claims 13-15 were canceled without prejudice or disclaimer and claims 1-12 amended. Claims 1-12 are pending in the instant application.

35 U.S.C. § 112, Second Paragraph

3. Claims 1-12 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims remain vague and indefinite for reciting claim limitations employing the term "about". Contrary to applicants' assertion, the phrase fails to clearly set forth the metes and bounds of the patent protection desired. For instance, claim 1 contains the phrases "about -5°C and +50°C" and "about 5 and about 9", which are vague and indefinite since the precise parameters of the claimed invention are not readily manifest. Appropriate correction is still required.

35 U.S.C. § 103(a)

4. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not
identically disclosed or described as set forth in section 102 of
this title, if the differences between the subject matter sought to
be patented and the prior art are such that the subject matter as
10 a whole would have been obvious at the time the invention was made
to a person having ordinary skill in the art to which said subject
matter pertains. Patentability shall not be negated by the manner
in which the invention was made.

15 Subject matter developed by another person, which qualifies as
prior art only under subsection (f) or (g) of section 102 of this
title, shall not preclude patentability under this section where the
subject matter and the claimed invention were, at the time the
invention was made, owned by the same person or subject to an
obligation of assignment to the same person.

20 5. This application currently names joint inventors. In
considering patentability of the claims under 35 U.S.C. § 103(a),
the examiner presumes that the subject matter of the various claims
was commonly owned at the time any inventions covered therein were
25 made absent any evidence to the contrary. Applicant is advised of
the obligation under 37 C.F.R. § 1.56 to point out the inventor and
invention dates of each claim that was not commonly owned at the
time a later invention was made in order for the examiner to
consider the applicability of 35 U.S.C. § 103© and potential 35
30 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

35 6. Claims 1-12 stand rejected under 35 U.S.C. § 103(a) as being
unpatentable over Kameyama et al. (1990) in view of Gao and Wilson
(2001). Applicants' arguments have been considered but are not
deemed to be persuasive. As previously set forth, Kameyama and
colleagues disclose methods for the inactivation of enveloped
viruses that are contaminating a protein-containing composition by
treating said compositions with 0.3% (w/v) TNBP and 1% (w/v) Tween
80 (see Examples 1 and 2, pp. 7 and 9, respectively). This

procedure resulted in the inactivation of various enveloped viruses (e.g., VSV or Sindbis virus) without adversely affecting the infectivity of a non-enveloped virus (e.g., Echo virus). Various routine experimental parameters are also described (e.g., % of TNBP, % of detergent, temperature ranges, conductivity ranges, pH ranges, etc.). Gao and Wilson (2001) disclose the medical importance of adenoviral vectors and their use in therapeutic compositions.

While Kameyama et al. (1990) do not disclose the inactivation of enveloped viruses in an adenoviral-containing preparation, nevertheless, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to subject viral preparations comprising both enveloped viruses and non-enveloped adenoviruses to the aforementioned treatments, since this would provide a means of ensuring the safety of non-enveloped adenoviral vector preparations for any one of a number of purposes such as gene therapy or diagnostic applications. Moreover, Kameyama et al. (1990) state (p. 3, l. 13-25) that "There is no particular limitation posed on the protein-containing liquid composition to which the method of the present invention is applied. Examples thereof include plasma or tissue extracts, solutions comprising a fraction obtained by treating plasma or tissue extract by various fractionation methods, culture broths obtained by culturing a gene recombinant host or tissue and commercially available protein preparations (in a liquid form) or their solutions." Thus, both the motivation and a reasonable expectation of success were present in the prior art.

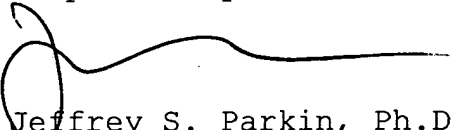
Correspondence

7. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703)

308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

8. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,


Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

06 September, 2003